

REMARKS

Claims 1-18 and 31 are pending in the present application. The following rejections remaining at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-18 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594); and

1. The Double Patenting Rejection Is Improper

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Responses. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-18 and 31 are rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594). Applicants must again respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.¹ In addressing this rejection, Applicants focus on the independent claims

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

since the non-obviousness of independent claims necessarily leads to the non-obviousness of the claims dependent thereon.²

1. The Examiner continues to ignore the appropriate standards for motivation to combine

As previously argued, the Examiner has failed to provide suitable evidence of a motivation to combine the cited references, thus a *prima facie* case of obviousness has not been established. In response to Applicants arguments, the Examiner made the following statement:

The "well-known" conclusion is supported by the teaching of Baltes et al. Cain et al. The instant claims are drawn to a method of making CLA and using CLA in food product. If the method of making CLA herein claimed is well-known, and using CLA in food product is well-known, the claimed method would have been obvious.

Applicants respectfully submit that this statement is a **misapplication of the law**.

Applicants previous arguments have highlighted the conclusory nature of the Examiner's reasoning regarding motivation to combine. This new statement by the Examiner provides a striking example of why the Examiner has not established a motivation to combine. The Examiner's basic argument is that **if** two things are well known (alcoholate catalysis and CLA in food), **then** the combination of the two things is well known (using CLA produced by alcoholate catalysis in food). This reasoning is completely devoid of any motivation to combine. Indeed, the only reasoning provided is that the two things are "well known."

The Federal Circuit has expressly forbidden this approach:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological

² §MPEP 2143.03.

advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).

In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998). In the instant application, the sole basis for combination is the allegedly "well-known" status of two separate concepts. The Examiner's combination on this basis is inadequate as a matter of law.

The Examiner has also failed to analyze the invention as a whole. When analyzed as a whole, the use of a method used for making CLA paint is non-obvious when the CLA is going to be utilized for food. "That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole." *Custom Accessories v. Jeffrey-Allan Industries Inc.*, 807 F.2d 955, 1 USPQ 2d 1196, 1198 (Fed. Cir. 1986); See also *Brantingson Fishing Equipment Co. v. Shimano American Corp.*, 9 USPQ 2d 1669, 1672 (Fed. Cir. 1988). Put another way: "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985) (quoting from Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)).

The *Fromson* case is particularly relevant here. In that case, the inventor developed a process for photolithography using 1) aluminum as a substrate, 2) oxide coatings by anodization, 3) silication, and 4) application of light-sensitive resins. The district court correctly found that each of these elements individually were known in the art - but incorrectly concluded, on the basis of the unpatentability of each element, that the combination of these steps was unpatentable. On appeal, the Federal Circuit pointed to the "fundamental error" of the district court, noting: "At no point did the court indicate, nor does the record indicate, a basis on which it can be said that the making of that combination would have been obvious when it was made." *Fromson*, *supra* at 31.

Accordingly, Applicants respectfully submit that the Examiner has not established a prima facie case of obviousness and that the claims should be passed to allowance.

2. The Examiner's reasoning demonstrates hindsight reconstruction

As previously argued, the Examiner's arguments are clear examples of hindsight reconstruction. In response to this argument, the Examiner has cited *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that:

[I]t must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

To the extent that this 1969 and 1971 C.C.P.A. cases appear to condone hindsight reconstruction when providing a motivation to combine references, the Federal Circuit has *sub silentio* overruled this proposition, and has emphatically stated that hindsight reconstruction is not proper (as detailed below).

The Federal Circuit has repeatedly warned against using hindsight reconstruction as a test of obviousness. A few examples of such cases include: *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention"); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed. Cir. 1990) (The inappropriateness of hindsight as a test of obviousness was, in point of fact, discovered, and articulated lucidly, over three centuries ago, by Milton, who, in *Paradise Lost* Part IV, L. 478-501, stated "The invention all admired, and each how he To be the inventor missed; so easy it seemed, Once found, which yet unfound would have thought, Impossible!"); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068 (Fed. Cir. 1993) ("The motivation to combine references can not come from the invention itself"); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest

that knowledge, is to use the invention as a template for its own reconstruction-an illogical and inappropriate process by which to determine patentability"); *W.L. Gore & Assocs., Inc. v. Garlock Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with the knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher ..."). Accordingly, to the extent the Examiner has admitted reliance on hindsight reconstruction, that reliance is misplaced as a matter of law.

3. The Examiner has ignored evidence presented by the Applicants that establishes that patentable weight should be given to the combination of adding alcoholate catalyzed CLA to food products.

As previously argued, the Examiner has essentially ignored the evidence contained in the Sæbo Declaration. In the present Office Action, the Examiner has again ignored the evidence and arguments advanced by the Applicants. Instead of addressing the evidence, the Examiner merely states that the Sæbo Declaration is unpersuasive as stated in the Office Action mailed December 21, 2001. This response fails to rebut either the arguments or the evidence advanced by the Applicants. This is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein.

Id.

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Sæbo Declaration, the Examiner has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. In particular, the Sæbo Declaration provides evidence that:

- "The Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic acid (CLnA) for technical purposes such as drying oils and paint varnishes.
- The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manners."
- Based on the disclosure of the Baltes, Cook and Lievens patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.
- Other disclosure in the Baltes patent also indicates the unsuitability of the methods for the production of edible CLA.
- The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunsaturated fatty acids.

These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated.

- However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

The only rebuttal of this evidence is provided in the Office Action dated December 28, 2001. The Examiner's attempted rebuttal, in its entirety, is as follows:

The declaration filed October 18, 2001, is insufficient to overcome the rejection of claims 1-30 set forth above: the teaching of Baltes et al. is not limited to the particular oil disclosed in the examples therein. Baltes teaches a general method for isomerizing unconjugated polyethenoid to conjugated polyethenoid. See, column 1, lines 13-16. The starting material may be any conjugated polyethenoid compounds or products containing them. See column 8, lines 20-68. Further, applicant appears to argue the employment of the reaction mixture to foodstuff, what is actually in the claims are the compounds, i.e., conjugated linoleic esters. ("to provide conjugated linoleic acid esters", see the claims in the instant application.

This response completely fails to respond to any of the points listed above. The Examiner states that Baltes is not limited to any particular oil. However, this fails to respond to the conclusion advanced by Mr. Sæbo that one skilled in the art would read the application to be directed to oils with high levels of triunsaturated fatty acids because a substitute for Tung oil was being sought. The Examiner further states that Baltes teaches the use of the resulting polyethenoid compounds for "any" product. However, this statement ignores the evidence advanced that a person of ordinary skill in the art would read Baltes as being directed to use of CLA for technical purposes, such as in paints in varnishes. Finally, the Examiner, states that "applicant appears to argue the employment of the reaction mixture to foodstuff" and dismisses the argument the claims are allegedly (and mistakenly) to compounds. This is precisely the point

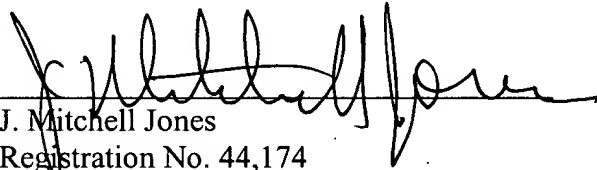
and indeed, what is claimed! **The use of the method of Baltes to produce CLA for use in foodstuffs is not obvious. As discussed above, it appears that the Examiner has failed to examine the invention as a whole.**

As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Sæbo Declaration. This evidence establishes that cited references cannot be properly combined to make the instant claims obvious. Accordingly, Applicants respectfully request that the claims be passed to allowance.

CONCLUSION

All grounds of rejection and objection of the Office Action of February 11, 2004, 2having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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